



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/841,426 04/24/01 NYCE

J EPI-00311

026380 HM22/0925
EPIGENESIS PHARMACEUTICALS
7 CLARK DRIVE
CANBURY NJ 08520

EXAMINER

JIANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

4
09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/841,426

Applicant(s)

NYCE, JONATHAN W.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a CIP of Serial No. 08/951,933 which is a continuation of 08/861,962 (patent 6,087,351) which is a divisional of 08/393,863 (patent 5,660,835).

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part), 7-14, and 15-48 (in part) drawn to pharmaceutical compositions and a kit comprising compounds having the chemical formula (I), classified in class 514, subclass 169 for example.
- II. Claims 1 (in part), 2-6, and 15-48 (in part) drawn to pharmaceutical compositions comprising compounds having the chemical formula (II), classified in class 514, subclass 169 for example.
- III. Claims 49-51 (in part), 52-53, 54 (in part), 55-56, and 61-79 (in part) drawn to an in vivo method of preventing or treating a disorder or condition associated with abnormal levels of adenosine and other conditions herein employing compounds having the chemical formula (I), classified in class 514, subclass 169 for example.
- IV. Claims 49-51 (in part), 54 (in part), 57-60, and 61-79 (in part) drawn to an in vivo method of preventing or treating a disorder or condition associated with abnormal levels of adenosine and other conditions herein employing compounds having the chemical formula (II), classified in class 514, subclass 169 for example.

Inventions Group I-II; and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, for example, mechlorethamin may be used in the treatment of cancer.

Each above product and method of treatment relates to a separate and distinct area of pharmaceutical technology. The search for all inventions would place an undue burden on the Office in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

1) a plurality of disclosed patentably distinct compounds in Groups I-IV (see above the restriction requirement); and

2) a plurality of disclosed patentably distinct diseases or conditions to be treated in Groups III-IV (see above the restriction requirement),

Applicant is required under 35 U.S.C. 121 to elect a composition comprising a specified combination of individual compounds for Groups I-IV and elect a single specified disease or condition to be treated for Groups III-IV for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-79 are generic to a plurality of disclosed patentably distinct species (compounds) and diseases to be treated. The claims of Groups I-IV read on the employment of various compounds of with great diversity of chemical structure classified across class 514 and the claims of Groups III-IV also read methods of treatment of unspecified diseases or conditions to be treated, the search for all of which presents an undue burden on the Office. It is noted that a reference to one combination of individual agents would not be a reference to another combination of individual agents under 35 U.S.C.103.

A "specie" is a specific compound and a specific disease or condition to be treated, with all parameters and/or substituent variables FULLY accounted for.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P Sec. 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

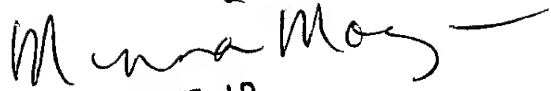
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

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Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
September 19, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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